# 510(k) Summary

MAY 1 4 2013

This summary of 510(k) safety and effectiveness information is furnished in accordance with requirements detailed in 21 CFR 807.92.

1.
**The assigned 510(k) number** is K-TBD

Submitter's Identification:
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Correspondence:

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Date of submission 07 December 2012

2.
**Device name:**

1. Fletcher type Applicator Set

Proprietary name: Kobold Fletcher Type GYN T&O Applicator Set™

2. Henschke type Applicator Set

Proprietary name: Henschke Type GYN T&O Applicator Set™

A. Regulation Section 892.5700
B. Classification: Class II
C. Product Code: JAQ
D. Panel: Radiology

3.
**Intended Use:**

1. The CT/MRI Compatible HDR Fletcher Type Applicator is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.

2. The CT/MRI Compatible HDR Henschke Type Applicator is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.

4.
**Device Description:**

1. The CT/MRI Compatible HDR Fletcher Type Applicator Set™ design is based on the conventional modified Fletcher GYN applicator with a click fit connector interface. This applicator is particularly useful in providing an HDR radiation boost to the cervix and parametrical tissues in conjunction with external beam radiation therapy. The set consists of precision manufactured intrauterine tandems and a pair of interlocking colpostats with Fletcher type unshielded ovoids ranging in size from 1cm to 3cm. All components are designed to allow for customization of the treated geometry. The distance between the ovoids is adjustable with a lock knob. Four different tandems are provided: one straight, one with a slight curvature of 15 degrees, one with medium curvature of 30 degrees, and one with a maximal curvature of 45 degrees.

2. The CT/MRI Compatible HDR Henschke Type Applicator Set™ design is based on the conventional modified Henschke GYN applicator with a click fit connector interface. This applicator is particularly useful in providing an HDR radiation boost to the cervix and parametrical tissues in conjunction with external beam radiation therapy. The set consists of precision manufactured intrauterine tandems and a pair of interlocking colpostats with Henschke type unshielded ovoids ranging in size from 2cm to 3cm. All components are designed to allow for customization of the treated geometry. The distance between the ovoids is adjustable with a lock knob. Four different tandems are provided: one straight, one with a slight curvature of 15 degrees, one with medium curvature of 30 degrees, and one with a maximal curvature of 45 degrees.

5.
**Substantial Equivalence Information:**

Information presented supports substantial equivalence of the Kobold Fletcher and Henschke Type GYN T&O Applicator Set™ to the predicate device. Each of the two proposed devices has the same indications for use, has similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same sterilization procedures. Please see predicate device brochure in Appendix C.

A. Predicate device names: Mick® Ring Type GYN Applicator Set
B. Predicate device K numbers: 011657
C. Comparison with predicate:

| **SUBSTANTIAL EQUIVALENCE TABLE** | KOBOLD LLC | KOBOLD LLC | MICK RADIO-NUCLEAR INSTRUMENTS, INC.® |
|---|---|---|---|
| K-Number | TBD | TBD | K-011657 |
| Device Description | Applicator Set, Fletcher Type | Applicator Set, Henschke Type | Applicator Set, Ring Type |
| Indications for Use | The CT/MRI Compatible HDR Fletcher Type Applicator is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines. | The CT/MRI Compatible HDR Henschke Type Applicator is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines. | The Mick Radio-Nuclear Instruments, Inc. HDR Tandem/Ring Applicator with Rectal Retractor is intended for use in Brachytherapy. The delivery of intra-cavitary radiation therapy requires not only proper visualization and localization of the applicator within the treatment volume, but precise dosimetry and a stable delivery system from which treatment can be administered. The Mick Radio-Nuclear HDR Tandem/Ring Applicator with Rectal Retractor meets these requirements. |
| Afterloader Compatibility | GammaMed®, VariSource® with click-fit connector. | GammaMed®, VariSource® with click-fit connector. | GammaMed®, VariSource® with click-fit connector. |
| Design Geometry | Flexible | Flexible | Flexible |
| Materials | Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl | Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl | Titanium, Stainless Steel, Polysulphone, Silicone |
| Packing | Tray | Tray | Cassette |
| Sterility | Provided Non-Sterile | Provided Non-Sterile | Provided Non-Sterile |
| Sterilization Methods, Sterilization Conditions, | Steam 18 min at 273°F (134°C), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented | Steam 18 min at 273°F (134°C), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented | Steam 20 min at 132°C Dry 15 min; no Sterrad® compatibility documented |

| | | | |
|---|---|---|---|
| Biocompatibility | Documented | Documented | Not Documented |
| Anatomical Sites | Uterus, Cervix | Uterus, Cervix | Cervix |
| Environmental Compatibility | CT/MRI Compatible | CT/MRI Compatible | CT/MRI Compatible |

6.

**Test Principle, Performance Characteristics:**

FDA has not established special controls or performance standards for this device.

7.

**Bench Top Testing**

Extensive testing in accordance with known standards is documented by the manufacturer. The standard is a specification for the materials used in surgical implant applications, predicate brachytherapy devices and manufacturer's acceptance procedures are detailed in Appendix A. Mechanical testing of the finished devices is additionally described in Appendix A.

8.

**Conclusions**

Both versions of Kobold's Applicator Set are similar in intended use and technological characteristics to predicate devices reviewed. Each of the two versions of the device is similar with respect to indications for use and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

**Contraindications:** As per clinical guidelines and standard clinical practice.

**Warnings and Precautions:** The precautions are provided in the device labeling for the Kobold Fletcher Style GYN T&O Applicator Set™ and Kobold Henschke Style GYN T&O Applicator Set™. There is no warning associated with this type of device.

9.

**Summary**

| **Description** | **Comparison with Predicate Device** |
|---|---|
| Biocompatibility | Safe as Predicate Device |

| | |
|---|---|
| Performance Characteristics | Substantially equivalent |
| Intended Use | Substantially equivalent |
| Performance Tests | Not Required |

Each version of the device 1. Kobold Fletcher Type GYN T&O Applicator Set™ and 2. Kobold Henschke Style GYN T&O Applicator Set™, based on the information submitted in this 510(k) application has been demonstrated to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Kobold, LLC
% Ms. Christina Bernstein
Regulatory Director
2670 Leavenworth Street
SAN FRANCISCO CA 94133

May 14, 2013

Re: K123912
Trade/Device Name: Fletcher Type GYN T&O Applicator Set™
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: April 19, 2013
Received: May 2, 2013

Dear Ms. Bernstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K123912

Device Name: Fletcher Type GYN T&O Applicator Set™

Indications for Use:

The CT/MRI Compatible HDR Fletcher Type Applicator is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.

Prescription Use __X__ AND/OR Over-The-Counter Use

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k)_____**K123912**_____